NOV 2 5 2013

K132544
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TomTec Imaging Systems, GmbH
Edisonstrasse 6
85716 Unterschleissheim

Traditional 510(k) Summary

- **TomTec-Arena 1.0**

Owner's Name and Address

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person

Mrs. Christine Klein
Phone +49-89-32175-830
Fax +49-89-32175-750

Common, Classification & Proprietary Names

Common Name: Various Image Analysis System Software
Classification Name: Picture Archiving and communications system
Programmable diagnostic computer

Proprietary Name: **TomTec-Arena 1.0**

Predicate Devices

Predicate Device 1	K071232	Image-Arena Applications, Research-Arena Applications : 4D RV-Function 1.0, 4D Cardio-View 2.0, 4D LV-Function 2.0
Predicate Device 2	K090461	Image-Arena 4.0 and Image-Arena Applications: 2D Cardiac Performance Analysis 1.0
Predicate Device 3	K103782	4D MV-Assessment 2.0
Predicate Device 4	K110595	4D Sono-Scan 1.0
Predicate Device 5	K110667	Image-Arena and Image-Arena Applications Image-Arena 4.5, Echo-Com 4.5, Image-Com 4.5
Predicate Device 6	K110746	4D LV-Analysis 3.0
Predicate Device 7	K120135	2D Cardiac Performance Analysis MR 1.0
Predicate Device 8	K122289	Image-Com 5.0

Device Description

TomTec-Arena is a clinical software package for reviewing, quantifying and reporting digital medical data. TomTec-Arena runs on high performance PC platforms based on Microsoft Windows operating system standards. The software is compatible with different TomTec Image-Arena™ platforms, their derivatives or third party platforms.
Platforms enhance the workflow by providing the database, import, export and other services. All analyzed data and images will be transferred to the platform for archiving, reporting and statistical quantification purposes.
TomTec-Arena consists of the following optional clinical application packages:

- Image-Com
- 4D LV-Analysis/Function
- 4D RV-Function
- 4D Cardio-View
- 4D MV-Assessment
- Echo-Com
- 2D Cardiac-Performance Analysis
- 2D Cardiac-Performance Analysis MR
- 4D Sono-Scan

Indications for use and Intended use

TomTec-Arena software is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities.
TomTec-Arena is not intended to be used for reading of mammography images.
Indications for use of TomTec-Arena software are diagnostic review, quantification and reporting of cardiovascular, fetal and abdominal structures and function of patients with suspected disease.

Technological Characteristics Comparison

The Subject Device "TomTec-Arena 1.0" contains clinical application packages (CAPs) for analysis of medical studies containing multimodal and multidimensional medical data.
The actual submission combines the advantages of the FDA cleared TomTec Imaging Systems software products:

Predicate Device 1	K071232	Image-Arena Applications, Research-Arena Applications : 4D RV-Function 1.0, 4D Cardio-View 2.0, 4D LV-Function 2.0
Predicate Device 2	K090461	Image-Arena 4.0 and Image-Arena Applications: 2D Cardiac Performance Analysis 1.0
Predicate Device 3	K103782	4D MV-Assessment 2.0
Predicate Device 4	K110595	4D Sono-Scan 1.0
Predicate Device 5	K110667	Image-Arena and Image-Arena Applications Image-Arena 4.5, Echo-Com 4.5, Image-Com 4.5
Predicate Device 6	K110746	4D LV-Analysis 3.0
Predicate Device 7	K120135	2D Cardiac Performance Analysis MR 1.0
Predicate Device 8	K122289	Image-Com 5.0

The Subject Device incorporates all functionalities within dedicated clinical application packages (CAPs) with the goal of enhancing the workflow when analysing multimodal and multidimensional medical data. The underlying technology of the Subject Device is identical to the Predicate Devices listed above.

Discussion according non-clinical performance data testing

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted.
The test procedure was performed according to the Project Quality Plan.
Test results were reviewed by designated technical professionals before software proceeded to release.
All requirements have been verified by tests or other appropriate methods.
The incorporated OTS Software is considered validated either by particular tests or implied by the absence of OTS SW related abnormalities during all other V&V activities.
The summary conclusions state that:

- all automated tests were reviewed and passed
- feature complete test completed without deviations
- functional tests are completed
- measurement verification is completed without deviations
- multilanguage tests are completed without deviations
- all non-verified bugs have been evaluated and are rated as minor deviations. They are deferred to the next release.

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Discussion according clinical performance data testing

Substantial equivalence determination of this subject device was not based on clinical data or studies.
The overall product concept was clinically accepted and supports the conclusion that the device is as safe as effective, and performs as well as or better than the predicate devices.

A clinical evaluation following the literature route based on the assessment of benefits, associated with the use of the device, was performed. The clinical evaluation shows that the published data are relevant and applicable to the relevant characteristics of the device under assessment and the medical procedure for which the device is intended.

Risk analysis aspects were treated in the risk management report. Based on this document the existing applied methods in the literature and the newly described techniques of the product (which are considered in the risk analysis) were evaluated.
No further risks were identified.

Conclusion from the analysis of the literature review

- The Risk-Benefit Assessment concludes that the benefit is superior to the risk, whereas the risk is low. The product TomTec-Arena is therefore harmless for patient and user and the advantages overbalance the probable risks of injury or illness for the patient.
- The data are sufficient to demonstrate compliance with the essential requirements covering safety and performance of the device in question under normal conditions of use.
- The claims made in the device labeling are substantiated by the clinical data.

Test Conclusions of non-clinical and clinical performance data

Test results support the conclusion, that the device is as safe as effective, and performs as well as or better than the predicate devices.

No reportable events or problems for the predicate devices exist.
The overall product concept was clinically accepted and the test results support the conclusion that the subject device is as safe as effective and performs as well as the predicate devices.

October 31, 2013

J. Waldinger
CTO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25, 2013

TOMTEC IMAGING SYSTEM, GmbH
% CHRISTINE KLEIN
QM & RA ASSISTANT
EDISONSTRASSE 6
UNTERSCHLEISSHEIM 85716
GERMANY

Re: K132544
Trade/Device Name: TomTec Arena 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 23, 2013
Received: October 28, 2013

Dear Ms. Klein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

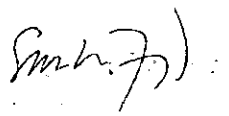
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132544

Device Name
TomTec-Arena 1.0

Indications for Use *(Describe)*

Indications for use of TomTec-Arena software are diagnostic review, quantification and reporting of cardiovascular, fetal and abdominal structures and function of patients with suspected disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*